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U.S. DISTRICT COURT  
NORTHERN DIST. OF TX.  
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JURY REQUESTED

*Pending Transfer to MDL-1699 (In re  
Celebrex and Bextra Marketing, Sales  
Practices and Prods. Liab. Litig.)*

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COME Defendants Jeanne L. Jalufka, Robert G. Vial, Erica Zeplin, and Lynsey Adame (hereinafter “Defendants”) and file this their Original Answer to Plaintiff’s First Amended Original Petition (“Complaint”), and would respectfully show the Court as follows:

## PRELIMINARY STATEMENT

The Complaint does not include any sufficient allegations against Defendants. Counts one (“Strict Products Liability Failure to Warn”), two (“Strict Products Liability Defective Product”), three (“Negligence”), four (“Breach of Implied Warranty”), five (“Breach of Express Warranty”), six (“Fraud”), and seven (“Fraud by Concealment”) of the Complaint merely assert

vague and conclusory allegations against “Defendants” generally, all of which fail as a matter of Texas law as to Defendants.

In addition, the Complaint does not state in sufficient detail when Plaintiff was prescribed or used Celebrex® (celocoxib) (“Celebrex®”). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Celebrex®.

### **ORIGINAL ANSWER**

#### **I.**

1. Answering the first unnumbered paragraph in Section I of the Complaint, Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required.

#### **II.**

#### **Response to Introduction and Allegations Regarding Parties**

2. Answering the first unnumbered paragraph in Section II of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis;

and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny that Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

3. Answering the second unnumbered paragraph of Section II of the Complaint, Defendants admit that Plaintiff claims to be a Texas citizen. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Answering the third unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Pfizer Inc. ("Pfizer") are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York, and that Pfizer does business in the State of Texas. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Answering the fourth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Jacqueline Guerrero are not directed toward Defendants and, therefore, no response is required.

6. Answering the fifth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Bob Davis are not directed toward Defendants and, therefore, no response is required.

7. Answering the sixth unnumbered paragraph in Section II of the Complaint, Defendants admit that Jeanne L. Jalufka may be served with process at her place of residence.

8. Answering the seventh unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Kyle M. Nelson are not directed toward Defendants and, therefore, no response is required.

9. Answering the eighth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Jason D. Hahn are not directed toward Defendants and, therefore, no response is required.

10. Answering the ninth unnumbered paragraph in Section II of the Complaint, Defendants admit that Robert G. Vial may be served with process in at his place of residence.

11. Answering the tenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Katheryn K. Truitt are not directed toward Defendants and, therefore, no response is required.

12. Answering the eleventh unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Kari A. McLuhan are not directed toward Defendants and, therefore, no response is required.

13. Answering the twelfth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Reynaldo Riojas are not directed toward Defendants and, therefore, no response is required.

14. Answering the thirteenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Francisco Meza are not directed toward Defendants and, therefore, no response is required.

15. Answering the fourteenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Jack Barineau are not directed toward Defendants and, therefore, no response is required.

16. Answering the fifteenth unnumbered paragraph in Section II of the Complaint, Defendants admit that Erica Zeplin may be served with process at her place of residence.

17. Answering the sixteenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Deborah Quinones are not directed toward Defendants and, therefore, no response is required.

18. Answering the seventeenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding W. Lance Goodson are not directed toward Defendants and, therefore, no response is required.

19. Answering the eighteenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Keeley Rodriguez are not directed toward Defendants and, therefore, no response is required.

20. Answering the nineteenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Leah Silva are not directed toward Defendants and, therefore, no response is required.

21. Answering the twentieth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Daniel Ponce are not directed toward Defendants and, therefore, no response is required.

22. Answering the twenty-first unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Celeste Escobar are not directed toward Defendants and, therefore, no response is required.

23. Answering the twenty-second unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Jill Guidry are not directed toward Defendants and, therefore, no response is required.

24. Answering the twenty-third unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Daniel Townsend are not directed toward Defendants and, therefore, no response is required.

25. Answering the twenty-fourth unnumbered paragraph in Section II of the Complaint, Defendants admit that Lynsey Adame may be served with process at her place of residence.

26. Answering the twenty-fifth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Clarence Brooks, M.D., are not directed toward Defendants and, therefore, no response is required.

### **III.**

#### **Response to Allegations Regarding Jurisdiction and Venue**

27. Answering the first unnumbered paragraph in Section III of the Complaint, Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that Plaintiff claims to be a resident of the State of Texas. Defendants admit that Jeanne L. Jalufka, Robert G. Vial, Erica Zeplin, and Lynsey Adame are residents of the State of Texas. Defendants admit that Plaintiffs claim that the amount in controversy exceeds minimum jurisdictional limits. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants no response is required. Defendants deny committing a tort within the State of Texas, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

28. Answering the second unnumbered paragraph in Section III of the Complaint, Defendants state that this paragraph of the Complaint contains legal contentions to which no response is

required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as the judicial district in which the asserted claims allegedly arose and, therefore, deny that venue is proper in Tarrant County, Texas. Defendants deny committing a tort within the State of Texas and deny the remaining allegations in this paragraph of the Complaint.

**IV.**  
**Response to Factual Allegations**

29. Answering the first unnumbered paragraph in Section IV of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that the allegations in this paragraph of the Complaint regarding Pfizer are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

30. Answering the second unnumbered paragraph in Section IV of the Complaint, Defendants admit that Celebrex® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for

relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Answering the third unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

32. Answering the fourth unnumbered paragraph in Section IV of the Complaint, Defendants state that, the allegations in this paragraph of the Complaint regarding Pfizer are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous



colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

33. Answering the fifth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

34. Answering the sixth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Answering the seventh unnumbered paragraph in Section IV of the Complaint, Defendants state that, the allegations in this paragraph of the Complaint regarding Pfizer are not

directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

36. Answering the eighth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

37. Answering the ninth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

38. Answering the tenth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed

toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

39. Answering the eleventh unnumbered paragraph in Section IV of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that the referenced press release and study speak for themselves and respectfully refer the Court to the press release and study for their actual language and text. Any attempt to characterize the press release and study is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

40. Answering the twelfth unnumbered paragraph in Section IV of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

41. Answering the thirteenth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that they are or were employed by Pfizer as pharmaceutical sales representatives and, at times, called on certain healthcare providers regarding Pfizer's products. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

42. Answering the fourteenth unnumbered paragraph in Section IV of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that the allegations in this paragraph of the Complaint regarding Pfizer and Defendant Brooks are not directed toward Defendants, and, therefore no response is required. Defendants deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

43. Answering the fifteenth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

## V.

### **Response to First Cause of Action: Strict Products Liability Failure to Warn**

44. Answering the first unnumbered paragraph in Section V of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations

regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

45. Answering the second unnumbered paragraph in Section V of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

46. Answering the third unnumbered paragraph in Section V of the Complaint, Defendants state that, the allegations in this paragraph of the Complaint regarding Pfizer are not directed

toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

47. Answering the fourth unnumbered paragraph in Section V of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

48. Answering the fifth unnumbered paragraph in Section V of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

49. Answering the sixth unnumbered paragraph in Section V of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations

regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

50. Answering the seventh unnumbered paragraph in Section V of the Complaint, Defendants state that, the allegations in this paragraph of the Complaint regarding Pfizer are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

51. Answering the eighth unnumbered paragraph in Section V of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that



Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**VI.**

**Response to Second Cause of Action: Strict Products Liability Defective Product**

52. Answering the first unnumbered paragraph in Section VI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Answering the second unnumbered paragraph in Section VI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.



54. Answering the third unnumbered paragraph in Section VI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

55. Answering the fourth unnumbered paragraph in Section VI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

56. Answering the fifth unnumbered paragraph in Section VI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its

FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

57. Answering the sixth unnumbered paragraph in Section VI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

58. Answering the seventh unnumbered paragraph in Section VI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

59. Answering the eighth unnumbered paragraph in Section VI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations

regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

## **VII.**

### **Response to Third Cause of Action: Negligence**

60. Answering the first unnumbered paragraph in Section VII of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

61. Answering the second unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

62. Answering the third unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

63. Answering the fourth unnumbered paragraph in Section VII of the Complaint, Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required.

64. Answering the fifth unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its

FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, Defendants deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

65. Answering the sixth unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny that Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

66. Answering the seventh unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny the remaining allegations in this paragraph of the Complaint.

67. Answering the eighth unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny that Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

68. Answering the ninth unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny that Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

69. Answering the tenth unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

70. Answering the eleventh unnumbered paragraph in Section VII of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

71. Answering the twelfth unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**VIII.****Response to Fourth Cause of Action: Breach of Implied Warranty**

72. Answering the first unnumbered paragraph in Section VIII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

73. Answering the second unnumbered paragraph in Section VIII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that Pfizer provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

74. Answering the third unnumbered paragraph in Section VIII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any



wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

75. Answering the fourth unnumbered paragraph in Section VIII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

#### **IX.**

##### **Response to Fifth Cause of Action: Breach of Express Warranty**

76. Answering the first unnumbered paragraph in Section IX of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that Pfizer provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

77. Answering the second unnumbered paragraph in Section IX of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not